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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,960	11/09/2001	Walter J. Stevens	STAN-132CIP	5625

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	Application No. 10/010,960	Applicant(s) STEVENS ET AL	
	Examiner Jessica R Baxter	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                              |                                                                             |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Specification*

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the term "structural means" is used.

Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-26, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,366,819 to Kaster.

Regarding claims 1, 7 and 25, Kaster discloses an anastomosis system comprising first (tube 12) and second structural means (ring 16 and ring 18), wherein each of said first and second

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structural means comprises a tubular region that terminates in a lip at one end (ring 16 and flange 14) , and further wherein said first and second structural means are capable of assuming a nested configuration (FIG. 1).

Regarding claims 2, 8, 16 and 26, Kaster discloses that the inner diameter of the tubular region of said second structural means (ring 16) is greater than the outer diameter of the tubular region of said first structural means (tube 12 FIG. 1).

~~Regarding claims 3 and 20, Kaster discloses that said first and second structural means are~~  
flexible (Column 10 lines 3-19).

Regarding claims 4 and 21, Kaster discloses that said first and second structural means are rigid (Column 10 lines 3-19).

Regarding claims 5 and 9, Kaster discloses that the first and second structural means are nested (FIG. 1).

Regarding claims 6 and 10, Kaster discloses that said first and second structural means are separate (Column 9 lines 53-60).

Regarding claim 11, Kaster discloses that each lip of said first and second structural means has a curvilinear configuration (FIGS 2 and 3).

Regarding claim 12, Kaster discloses that said curvilinear configuration of said lip of said first structural means is different from said curvilinear configuration of said lip of said second structural means (FIG. 1 ring 16 and flange 14).

Regarding claim 13, Kaster discloses that the length of the tubular region of the second structural means is less than the length of the tubular structure of the first structural means (FIG. 1).

Regarding claim 14, Kaster discloses a vessel (vein 20) inserted through first (tube 12) and second structural means (rings 16 and 18), wherein said first and second structural means each have

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a tubular region that terminates at one end in a lip ( flange 14 and ring 16 FIG. 6), and wherein said first and second structural means are capable of assuming a nested configuration (FIGS. 1 and 6).

Regarding claims 14 and 15, Kaster discloses that the end of said vessel (vein 60) is everted over the distal surface and at least a portion of the proximal surface of the lip (lip 52g) of said first structural means (FIG. 9).

Regarding claims 17-19 and 28, Kaster discloses that the vessel is a naturally occurring vessel,

~~a vascular vessel, or a synthetic vessel (Column 4 lines 62-68).~~

Regarding claim 22, Kaster discloses a method for performing an end-to-side anastomosis, said method comprising: (a) preparing an opening in a host vessel (hole 22a); (b) inserting into said opening the end of a prepared graft vessel having a graft vessel threaded through first and second structural means wherein each of said first and second structural means has a tubular region that terminates at one end in a lip, wherein the end of said graft vessel is everted over the distal surface and at least a portion of the proximal surface of the lip of the first structural means; and (c) sliding said second structural means over the tubular region of said first structural means in a manner sufficient to stably attach said graft vessel to said host vessel and establish fluid communication between the lumens of said graft and host vessels; whereby said end-to-side anastomosis is performed (Column 14 lines 15-53).

Regarding claims 23-24, Kaster discloses that wherein said graft vessel is prepared by: sequentially inserting said graft vessel through the tubular regions of said first and second structural means; and everting the end of said graft vessel over the distal surface and at least a portion of the proximal surface of the lip of said first structural means (FIG. 9 and Column 14 lines 15-53).

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Regarding claim 29, Kaster discloses that said kit further comprises a delivery means (Column 11 lines 37-66).

Regarding claim 30, Kaster discloses that said kit further comprises a structural means holder for use in preparation of a graft vessel (ringflange 54).

5. Claims 1-13 and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,007,576 to McClellan.

~~Regarding claims 1, 7 and 25, McClellan discloses an anastomosis system comprising: first~~  
and second structural means (element 10 and element 20), wherein each of said first and second structural means comprises a tubular region (tubular portions 11 and 21) that terminates in a lip (flanges 12 and 23) at one end, and further wherein said first and second structural means are capable of assuming a nested configuration (FIG. 2).

Regarding claims 2, 8 and 26, McClellan discloses that the inner diameter of the tubular region (tubular portion 21) of said second structural means is greater (FIG. 2) than the outer diameter of the tubular region of said first structural means (portion 11).

Regarding claim 3, McClellan discloses that said first and second structural means are flexible (Column 4 lines 44-62).

Regarding claim 4, McClellan discloses that said first and second structural means are rigid (Column 4 lines 44-62).

Regarding claims 5 and 9, McClellan discloses that said first and second structural means are nested (FIG. 2).

Regarding claims 6 and 10, McClellan discloses that said first and second structural means are separate (FIG. 1).

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Regarding claim 11, McClellan discloses each lip of said first and second structural means has a curvilinear configuration (FIG. 7 and 8).

Regarding claim 12, McClellan discloses that said curvilinear configuration of said lip of said first structural means is different from said curvilinear configuration of said lip of said second structural means (FIG. 11).

Regarding claim 13, McClellan discloses that the length of the tubular region of the second structural means is less than the length of the tubular structure of the first structural means (FIG. 11).

Regarding claim 27, McClellan discloses that said kit comprises a plurality of said anastomosis systems (Column 8 lines 1-8).

Regarding claim 28, McClellan discloses that said kit further comprises a synthetic vessel (Column 3 lines 7-13).

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to nested anastomosis devices:

U.S. Patent No. 5,188,638 to Tzakis

U.S. Patent No. 5,725,544 to Rygaard

U.S. Patent No. 5,993,468 to Rygaard

U.S. Patent No. 6,206,913 to Yencho et al.

U.S. Patent No. 6,241,743 to Levin et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

jrb

July 9, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700